

REMARKS

Upon receipt of the Office Action, Claims 1-11 were pending. Claims 3-6, 8 and 11 are withdrawn from consideration as being directed to non-elected subject matter. Claim 2 is cancelled herein. Claims 1, 7, 9 and 10 are amended herein to place them in better condition for allowance, as discussed in detail below. The amendments to the claims are fully supported by the specification as originally filed and do not constitute new matter. Accordingly, entry of the amendments and reconsideration of the claimed subject matter is respectfully requested in view of the following remarks.

Acknowledgement of Election of Group I

The Examiner acknowledged Applicants' election of Group I *without traverse*.

Rejection of Claims 1, 2, 7, 9 and 10 under 35 U.S.C. 112, ¶ 2

The Examiner rejected Claims 1, 2, 7, 9 and 10 under 35 U.S.C. 112, ¶2, as allegedly being indefinite. In particular, the Examiner contended that these claims are indefinite because "Claims 1 and 2 lack a period at the end" and because "Claims 7 and 10 recite the phrase "particularly in" and "possibly in".

Claim 2 is cancelled herein, thereby rendering moot this rejection with respect thereto.

Claim 1 is amended herein to insert a period at the end of the claim. Claim 7 is amended herein to recite the steps of the claimed process of preparing crystalline form A of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol hydrochloride. Claim 10 is amended herein to recite the components of the claimed pharmaceutical composition.

In addition, "What is Claimed Is" inserted before Claim 1 to identify the beginning of the claims. Furthermore, the numbers of Claims 1, 7, 9 and 10 are amended to replace the right parenthesis with a period. Claim 1 is additionally amended to clarify the characterization of crystalline form A of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol hydrochloride.

In view of these amendments, Applicants respectfully submit that Claims 1, 7, 9 and 10 are definite under 35 U.S.C. 112, ¶2, and therefore respectfully request that the rejection of these claims under 35 U.S.C. 112, ¶2, be withdrawn.

Double Patenting

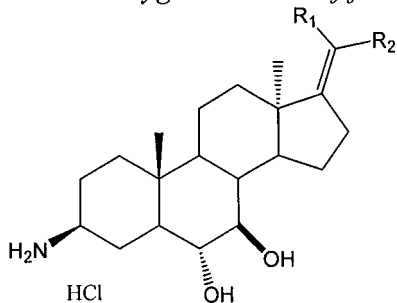
The Examiner objected to Claim 2 under 37 CFR 1.75 for allegedly being a substantial duplicate of Claim 1. Although Applicants disagree with the Examiner's reasons for this

objection, in the interest of furthering the allowance of this application, Claim 2 is cancelled herein, thereby rendering moot this objection with respect thereto.

Rejection of Claims 1, 2, 9 and 10 under 35 U.S.C. 102(b)

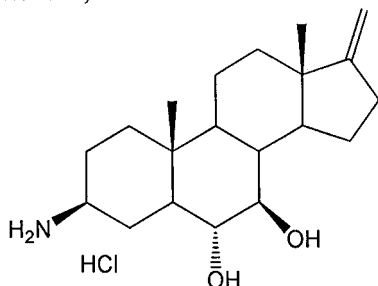
The Examiner rejected Claims 1, 2, 9 and 10 under 35 U.S.C. 102(b) as allegedly being anticipated by PCT Published Patent Application No. WO 01/83512 ("Raymond *et al.*"). In particular, the Examiner contends that:

Raymond et al. teaches salts of 3 β -amino-6,7-dihydroxy-17-methylidene steroids oxygen steroids of formula:



wherein R₂ is hydrogen and R₁ is hydrogen, methyl, ethyl, propyl, butyl or pentyl (see the entire article, especially Abstract, page 30, Scheme E; claims 11, 12; page 63, Synthesis of Compound 28; page 22, lines 26-32).

The court has held that a prior art directed to a recognizable small class of compounds, having common properties which embrace the claimed compound, herein,



, is anticipatory notwithstanding the fact the claimed compound is not specifically named. In re Schaumann et al. (CCPA 1978) 572 F.2d 312, 197 USPQ 5; In re Petering et al. (CCPA 1962) 301 F.2d 676, 133 USPQ 275.

The recitation of X-ray diffraction pattern or unit cell parameters at 296 K is noted. However, the recitation of unknown property that is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 1995 USPQ 430, 433 (CCPA 1977).

Claim 2 is cancelled herein, thereby rendering moot this rejection with respect thereto.

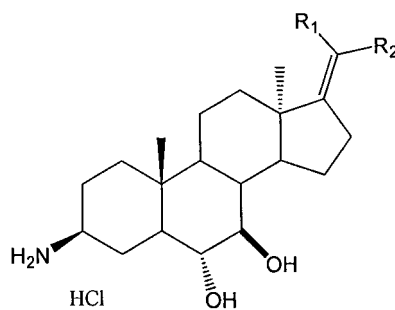
Applicants respectfully traverse this rejection with respect to Claims 1, 9 and 10 for the following reasons.

Claim 1 is directed to a specific crystalline form of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol hydrochloride having the indexing of the initial 30 rays of the powder X-ray diffraction pattern diagram at 295° K as set forth therein. Claim 9 is directed to this specific crystalline form as a medication to treat inflammatory illnesses or asthma and Claim 10 is directed to a pharmaceutical composition comprising this specific crystalline form.

This specific crystalline form of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol hydrochloride is not anticipated by or inherent in the teachings of Raymond *et al.*

Although Raymond *et al.* does disclose a genus encompassing the hydrochloride salt of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol, Raymond *et al.* does not specifically disclose the preparation of the hydrochloride salt of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol and certainly does not disclose how to make any crystalline forms of the hydrochloride salt, let alone crystalline form A of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol hydrochloride as set forth in Claims 1, 9 and 10. Raymond *et al.* only specifically discloses the preparation of the acetate salt of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol (see the preparation of Compound 89 on page 65 therein) and, in so doing, does not disclose whether this acetate salt is amorphous or crystalline.

The Examiner alleges that crystalline form A of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol is inherently present in the group of compounds encompassed by the following formula in Reaction Scheme E of Raymond *et al.*:



wherein R₂ is hydrogen and R₁ is hydrogen, methyl, ethyl, propyl, butyl or pentyl. However, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." See, *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner has not provided any evidence to support the allegation that crystalline form A of 3-beta-amino-17-

methylene-androstane-6-alpha,7-beta-diol hydrochloride would necessarily result from the preparation of the hydrochloride salt of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol from the teachings of Raymond *et al.*, particularly in the absence of any teaching in Raymond *et al.* as to the physical form of the salts (amorphous or crystalline) of the only related compounds specifically prepared therein.

Furthermore, "[i]nherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not enough." *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). There is no clear case to show that a hydrochloride salt of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol prepared by the teachings of Raymond *et al.* would, in fact, be crystalline form A.

Applicants therefore respectfully submit that there is no teaching or disclosure in Raymond *et al.* of crystalline form A of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol hydrochloride, as set forth in Claims 1, 9 and 10. Applicants further respectfully submit that crystalline form A of 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol hydrochloride is not "inherently" present in the genus of compounds which encompasses 3-beta-amino-17-methylene-androstane-6-alpha,7-beta-diol hydrochloride as set forth in Raymond *et al.* Accordingly, Applicants respectfully request the withdrawal of the rejection of Claims 1, 9 and 10 under 35 U.S.C. 102(b) in view of Raymond *et al.*

In view of the foregoing remarks and amendments, Applicants respectfully submit that Claims 1, 7, 9 and 10 are in condition for allowance. Reconsideration of these claims and early issuance of a Notice of Allowance is therefore respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
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